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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,306	11/07/2000	Li-Wei Hsu	205032000400	1255

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M

Office Action Summary**Application No.**

09/708,306

Applicant(s)

HSU ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-20 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-20 and 25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's response filed March 29, 2004 is acknowledged and has been entered. Currently, claims 14-20 and 25-31 are pending and are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 14, 15, 17, 19, 20, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515) for reasons of record.

3. Claims 16, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515) as applied to claims 14, 15, 17, 19, 20, and 25-27 above, and in further view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) or Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997) for reasons of record.
4. Claims 18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US Patent 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515) as applied to claims 14, 15, 17, 19, 20, and 25-27 above, and in further view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)) for reasons of record.
5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) in view of Upadhyay et al. (US Patent 5,962,515) as applied to claims 14, 15, 17, 19, 20, and 25-27 above, and in further view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)) or Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997), and further in view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)) for reasons of record.

Response to Arguments

6. Applicant's arguments filed 3/29/04 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of Burmer with Upadhyay does not teach or suggest all the elements of the claimed invention. Applicant specifically contends that column 8, lines 12-65 of Burmer discloses only general recombinant nucleic acid methods, methods of isolating nucleic acids, and making cDNA libraries. According to Applicant, there is no disclosure in Burmer of protein libraries or plant protein extracts extracted from any plant source; thus the disclosure has not provided a single citation that teaches and suggests the use of protein extracted from plants as the immobilized target in a selection assay.

Contrary to Applicant's argument, the teaching of Burmer at column 8, lines 43-46 and 55-60 provides that nucleic acid is extracted from tissue such as plant tissue, to yield fractions (fragments) which are separated by gradient centrifugation. The fractions in the claimed invention, as currently recited, do not appear to exclude nucleic acid fragment fractions which are separated by gradient centrifugation.

In response to Applicant's argument that the disclosure does not provide a single citation that teaches and suggests use of protein libraries or protein extracted from plants as the immobilized target, it is noted that the feature upon which applicant relies (i.e., use of protein libraries or protein extracted from plants as the immobilized target) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Independent claim 14 recites, "A method to screen plant extract for compounds that bind selectively to target", wherein the fractions [which presumably contain compounds] are each coated

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(immobilized) at different locations on a solid support for subsequent contact with a labeled target. Hence, as recited, the fractions that are extracted from plants, include compounds which are immobilized but not limited to proteins. These compounds are contacted with a labeled target, in this case, a protein (claim 17) or a glycoprotein (claim 18), which then complexes with the compound from the extract. Accordingly, Applicant's argument is not on point.

B) Applicant argues that the claimed method does not position individual components of the libraries on a substrate that allows immediate identification of individual target polypeptides. Instead, the claimed method positions individual fractions of plant extracts on substrate wherein each fraction contains multiple different components that share a similar molecular weight and charge; therefore, it is impossible to identify individual target polypeptides such as taught in the method of Burmer.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., protein libraries and that each fraction in the claimed method contains multiple different components that share a similar molecular weight and charge) is not recited in the rejected claims. Additionally, the recitation of "coating each fraction [containing compound] individually on a solid support" does not appear to exclude the teaching of Burmer which teaches providing a library of ligands, each ligand having a ligand address that corresponds to a tag address. Accordingly, the disclosure of Burmer reads on the claimed invention.

C) Applicant argues that Upadhyay fails to remedy the deficiencies of Burner and Apadhyay's disclosure regarding fractionation teaches away from the claimed method. Applicant specifically contends that Upadhyay uses repeated extractions under specific conditions to identify compounds active in biological assays from a single plant; hence, Upadhyay is completely silent with regards to any other plant other than *Piper longum*.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Burner discloses a method and kit to screen compound arrays (ligands), i.e. small organic molecules, extracted from plant wherein the compounds bind selectively to a target protein. The method is used to screen and detect for binding of a labeled target to any of the compound arrays. The compound libraries are arrayed spatially in a matrix, are contacted with a labeled target, incubated, washed with a buffer to remove unbound components, then detected for any complexes comprising the compound and labeled target protein. Burner discloses that the screening method finds use in pharmaceutical drug discovery. Upadhyay et al. is incorporated with the teaching of Burner only for the

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disclosure of using chromatographic methods to fractionate a crude plant extract. Thus, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to extract and fractionate compounds from crude plant as taught by Upadhyay for incorporation into a screening method for detecting biological activity as taught by Burmer because Upadhyay specifically taught that compounds are conventionally extracted and purified from plant sources for use in drug discovery screening assays and both of Burmer and Upadhyay specifically suggested using compounds extracted, purified, or isolated from plant to determine protein-ligand interaction for screening biological activity, i.e. immunomodulatory activity, in drug discovery of compounds.

D) Applicant argues that the addition of Baek, Verma, and Kutsuna to the teaching of Burmer and Upadhyay does not remedy the deficiency of Burmer and consequently does not suggest the claimed invention because none of them teach or suggest the use of target-binding properties to identify compounds in plant extracts. Hence, Applicant contends that the combination of references is improper and does not support the obviousness rejection.

In response, Baek et al. or Verma et al. are incorporated with the teaching of Burmer and Upadhyay only for the disclosure of a plant extract from an herb, which is *Carthamus tinctorius* wherein compounds were isolated by column chromatographies and have antithrombotic capacity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to screen an extract of the plant *C. tinctorius* as taught by Baek or Verma for compounds with biological activity, i.e. antithrombotic

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activity, using the method and kit of Burmer as modified by Upadhyay, because both of Burmer and Upadhyay et al. specifically taught application of their simultaneous screening method for drug discovery of lead pharmacological compounds including those comprising small organic molecules such as those from plant extracts such as C. Tinctorius herbs as in the teaching of Baek or Verma.

Kutsuna et al. was also incorporated with the teaching of Burmer and Upadhyay for the disclosure that a biologically active compound from safflower Carthamus tinctorius is a platelet aggregation inhibitor which exhibits in vivo anti-thrombotic activity, and which inhibits glycoprotein (GPIIb/IIIa) binding to serum proteins. The compound is induced by adenosine diphosphate, and is identified as adenosine. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the protein taught in the method of Burmer as modified by Upadhyay with glycoprotein or a platelet membrane receptor protein as taught by Kutsuna to screen an extract of plant for compounds having biological activity, i.e. platelet aggregation inhibition, because Burmer and Upadhyay specifically taught application of his simultaneous screening method for drug discovery of lead pharmacological compounds including those comprising small organic molecules from plant extracts that are capable of platelet aggregation inhibition, affecting platelet membrane receptor glycoprotein IIb/IIIa as in the teaching of Kutsuna.

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

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Gailene R. Gabel

Patent Examiner

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June 17, 2004 *gb*

Christopher L. Chin

CHRISTOPHER L. CHIN

PRIMARY EXAMINER

GROUP ~~1800~~ 1641